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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,052	06/02/2005	Allan Shepard	2335 US F	8397

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,052	SHEPARD ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) *3-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed September 2, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

a. Claim 1 has been amended.

2. Claims 1, 3-8 are pending in the case.

3. Claim 1 is present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). The modes of administration

include topical administration (paragraph 192) and liquid/solution forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods. One of skill in the art would immediately envision topical forms for neovascular glaucoma as topical forms are taught by Banerjee, treatment for the condition is taught by Banerjee, and it is the most common form of administration for ophthalmic conditions wherein one of skill in the art would immediately envision it. Inhibition of angiogenesis in neovascular glaucoma inherently reduces intraocular pressure as it is known in the art that neovascular glaucoma is a result of the angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure. Inhibition of angiogenesis inherently inhibits the cascade and lowers the intraocular pressure.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Alternatively, for completeness of prosecution, purely arguendo for this claim, insofar that the recitation of lowering intraocular pressure is not specifically recited, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). The modes of administration include topical administration (paragraph 192) and liquid/solution forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods.

It would be obvious to one of skill in the art to utilize the method for inhibiting angiogenesis as taught by Banerjee et al. comprising administering a composition comprising a nucleoside, particularly tunicamycin for conditions such as neovascular glaucoma for lowering intraocular pressure as it is known in the art that neovascular glaucoma is characterized by increased intraocular pressure resulting from angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure (evidenced by Gurwood et al., Discussion; Hunter et al., U.S. Pat. 5886026 line 47-Col. 34 line 18, U.S. Pat. Pub. 2002/0192280 paragraph 139-140). It would have been obvious to utilize a method that treats and inhibits the angiogenic source of neovascular glaucoma, to treat, inhibit, and reduce the resulting consequences of neovascular glaucoma such as intraocular pressure. It would also be obvious to one of skill in the art to utilize topical forms of tunicamycin for neovascular

glaucoma as topical forms are taught by Banerjee, treatment for the condition is taught by Banerjee, and it is the most common form of administration for ophthalmic conditions wherein it would be obvious to one of skill in the art to utilize the taught topical form for the condition which is commercially the most common form for ophthalmic administration.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a product to treat not only the condition but also its resulting consequences with taught modes of administration that are also the most commercially popular and accepted ophthalmic administration forms (topical).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-

104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). The modes of administration include topical administration (paragraph 192) and liquid/solution forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods. One of skill in the art would immediately envision topical forms for neovascular glaucoma as topical forms are taught by Banerjee, treatment for the condition is taught by Banerjee, and it is the most common form of administration for ophthalmic conditions wherein one of skill in the art would immediately envision it. Inhibition of angiogenesis in neovascular glaucoma inherently reduces intraocular pressure as it is known in the art that neovascular glaucoma is a result of the angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure. Inhibition of angiogenesis inherently inhibits the cascade and lowers the intraocular pressure.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Alternatively, for completeness of prosecution, purely arguendo for this claim, insofar that the recitation of lowering intraocular pressure is not specifically recited, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). The modes of administration include topical administration (paragraph 192) and forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods.

It would be obvious to one of skill in the art to utilize the method for inhibiting angiogenesis as taught by Banerjee et al. comprising administering a composition comprising a nucleoside, particularly tunicamycin for conditions such as neovascular glaucoma for lowering intraocular pressure as it is known in the art that neovascular glaucoma is characterized by increased intraocular pressure resulting from angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure (evidenced by Gurwood et al., Discussion; Hunter et al., U.S. Pat. 5886026 line 47-Col. 34 line 18, U.S. Pat. Pub. 2002/0192280 paragraph 139-140). It would have been obvious to utilize a method that treats and inhibits the angiogenic source of neovascular glaucoma, to treat, inhibit, and reduce the resulting consequences of neovascular glaucoma such as intraocular pressure. It would also be obvious to one of skill in the art to utilize topical forms of tunicamycin for neovascular

glaucoma as topical forms are taught by Banerjee, treatment for the condition is taught by Banerjee, and it is the most common form of administration for ophthalmic conditions wherein it would be obvious to one of skill in the art to utilize the taught topical form for the condition which is commercially the most common form for ophthalmic administration.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a product to treat not only the condition but also its resulting consequences with taught modes of administration that are also the most commercially popular and accepted ophthalmic administration forms (topical).

Response to Arguments

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Applicant's arguments filed 9/2/2009 have been fully considered but they are not persuasive. Applicant asserts that Banerjee et al. does not teach a method of lowering intraocular pressure with the administration of a cathepsin K antagonist and that the reference does not teach topical administration to the eye. This is not persuasive as Banerjee teaches treatment of neovascular glaucoma with a nucleoside, particularly tunicamycin which is also a cathepsin K antagonist, and it is known in the art that neovascular glaucoma is characterized with intraocular pressure and that the intraocular pressure in neovascular glaucoma is a result of angiogenesis. The inhibition of the angiogenesis would inherently inhibit the cascade in neovascular glaucoma affecting

the intraocular pressure which has been known and pursued in the art for many years. It is also known in the art that most angiogenic inhibitors have intraocular pressure reducing properties (e.g. Clark-U.S. Pat.6172054, Col. 1 line 50-66). The argument that the reference does not teach topical administration to the eye has been fully considered by are not persuasive as Banerjee does teach topical modes of administration and treatment of neovascular glaucoma utilizing forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods, wherein one of skill in the art would immediate envision topical administration for treatment of neovascular glaucoma.

Accordingly, the rejection is maintained.

11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Applicant's arguments filed 9/2/2009 have been fully considered but they are not persuasive. Applicant asserts that Banerjee et al. does not teach a method of lowering intraocular pressure with the administration of a cathepsin K antagonist and that the reference does not teach topical administration to the eye. This is not persuasive as Banerjee teaches treatment of neovascular glaucoma with a nucleoside, particularly tunicamycin which is also a cathepsin K antagonist, and it is known in the art that neovascular glaucoma is characterized with intraocular pressure and that the intraocular pressure in neovascular glaucoma is a result of angiogenesis. The inhibition of the angiogenesis would inherently inhibit the cascade in neovascular glaucoma affecting the intraocular pressure which has been known and pursued in the art for many years. It is also known in the art that most angiogenic inhibitors have intraocular pressure

reducing properties (e.g. Clark-U.S. Pat.6172054, Col. 1 line 50-66). The argument that the reference does not teach topical administration to the eye has been fully considered by are not persuasive as Banerjee does teach topical modes of administration and treatment of neovascular glaucoma utilizing forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods, wherein one of skill in the art would immediate envision topical administration for treatment of neovascular glaucoma.

Accordingly, the rejection is maintained.

12. Alternatively, for completeness of prosecution, purely arguendo for this claim in regards to Banerjee et al. (U.S. Pat. Pub. 2002/0160979) in the 102(a) and 102 (e) rejection above: Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Applicant's arguments filed 9/2/2009 have been fully considered but they are not persuasive. Applicant asserts that Banerjee et al. does not teach a method of lowering intraocular pressure with the administration of a cathepsin K antagonist, not a nucleoside; and that the reference does not teach topical administration to the eye. This is not persuasive as Banerjee teaches treatment of neovascular glaucoma with a nucleoside, particularly tunicamycin which is also a cathepsin K antagonist (a cathepsin K antagonist describes what it does, not what it is so a nucleoside e.g. tunicamycin which is claimed, can also have cathepsin K antagonist activity), and it is known in the art that neovascular glaucoma is characterized with intraocular pressure and that the intraocular pressure in neovascular glaucoma is a result of angiogenesis. The inhibition of the angiogenesis would inherently inhibit the cascade in neovascular glaucoma

affecting the intraocular pressure which has been known and pursued in the art for many years. It is also known in the art that most angiogenic inhibitors have intraocular pressure reducing properties (e.g. Clark-U.S. Pat.6172054, Col. 1 line 50-66). The argument that the reference does not teach topical administration to the eye has been fully considered by are not persuasive as Banerjee does teach topical modes of administration and treatment of neovascular glaucoma utilizing forms with a pharmaceutically acceptable carrier (paragraph 193-195) for the therapeutic methods, wherein it would be obvious to one of skill in the art to use the taught modes of administration such as topical administration for treatment of neovascular glaucoma. One is motivated to do so as it is the most common form of ophthalmic administration. Applicant's arguments in regards to Hunter and Gurwood are not persuasive as they are utilized to show that intraocular pressure is characteristic for neovascular glaucoma and as Banerjee teaches treatment of neovascular glaucoma, it would intrinsically treat the symptoms of neovascular glaucoma including intraocular pressure as addressed above and claimed in Banerjee.

Accordingly, the rejection is maintained.

Conclusion

13. Claim 1 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612